

REMARKS

Reconsideration and allowance by the Examiner of amended Claims 49, 61, 62, 65, 82 and 83 and previously presented Claims 41-48, 50-60, 63, 64, 66-81 and 84 are respectfully requested in light of the remarks which follow.

The drawings submitted on July 3, 2000 have been objected to by the Examiner. Enclosed is a set of formal drawings which show all of the features in currently amended Claim 65.

Claims 82 and 83 have been objected to by the Examiner under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 82 and 83 have been amended to correct the dependencies. Claim 82 now depends from Claim 78 and Claim 83 now depends from Claim 79. The duplicative limitations of original Claim 82 and original Claim 83 have been eliminated. Therefore, the objection to Claims 82 and 83 is respectfully requested to be withdrawn.

Claims 49, 61 and 62 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to Claim 49, Applicant has amended the claim as noted above to include a limitation which clarifies the range of median lengths to median widths to exclude any overlap in the ranges of median length and median width.

With regard to Claims 61 and 62, Applicant has amended the claims as noted above to better define the weight ratio of nondemineralized bone particles to demineralized bone particles to exclude a ratio containing a numerator or

denominator of zero. In light of the above-described amendments, the rejection of Claims 49, 61 and 62 under 35 U.S.C. § 112 has been overcome.

Claims 41-61, 63-65, 67 and 69-84 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,507,813 to Dowd et al. ("Dowd"). The Examiner asserts that "the recitation 'about 32%' for a maximum void volume is met by Dowd since the use of 'about' is broad and can reasonably be interpreted to include a variance of  $\pm$  5%". The Examiner has mistakenly calculated that a variance of  $\pm$  5% translates into a variance of the limitation of 37% to up to 42% and to a lower limit of 32%. It is noted for the Examiner that a correctly calculated variance of  $\pm$  5% involves multiplying .05 times the amount of the specific units being utilized for which one wishes to obtain a variance and does not involve merely and arbitrarily adding/subtracting 5 units of the chosen amount. As it pertains to Claims 41 and 77 and the claims which depend therefrom, a variance of 5% entails a range of from 1.85% below the Dowd percentage of 37% and 1.85% above 37%. This is calculated in a manner of multiplying .05 times the Dowd percentage of 37% which is 5% of 37%. The Examiner's range of  $\pm$  5% of the actual units of weight percentage translates into an actual variance of  $\pm$  13.51%.

The Applicant is aware of no case in which a numerical value that can be precisely determined has been extended by a variance of more than 10%. Even if the Examiner were to use a variance of 10%, this would still only translate into a range of 37%  $\pm$  3.7% and would thus set the lower limit of Dowd at 33.3%.

With regard to Claims 45, 46, 73, 75 and the claims which depend therefrom which pertain to the density of the claimed osteoimplant, the same arguments apply with equal force herein. The Examiner's range of the variance of  $\pm$  5% of the

claimed density of greater than .8g/cm<sup>3</sup> is not a range of  $\pm$  5g/cm<sup>3</sup> or from .3g/cm<sup>3</sup> to .13g/cm<sup>3</sup>. The properly calculated variance would be  $\pm$  5% of .8g/cm<sup>3</sup> which translates into a range of  $\pm$  .04g/cm<sup>3</sup> or from .76g/cm<sup>3</sup> to .84g/cm<sup>3</sup>. The Examiner's miscalculated use of the variance to yield a variance of  $\pm$  .5g/cm<sup>3</sup> is in actuality a variance of 62.5%.

The Applicant is aware of no case in which a numerical value that can be precisely determined has been extended by more than 10%, and certainly not to the extent of 62.5%.

With regard to Claim 70 and the claims which are dependent therefrom, the same argument applies with equal force herein. The Examiner's range of the variance of  $\pm$  5 mm of the claimed thickness of 2000 microns is not properly calculated. The proper variance of  $\pm$  5% of 2000 microns would be  $\pm$  100 microns or a range of from 1900 microns to 2100 microns. This variance of  $\pm$  100 microns converts into  $\pm$  .1 mm. Thus, the properly calculated variance of  $\pm$  5% is a variance of  $\pm$  .1 mm and not  $\pm$  .5 mm.

In light of the above remarks relating to Claims 41-61, 63-65, 67, 69-84, the Applicant believes the above-noted rejections to be overcome and thus respectfully requests allowance of said claims.

The Examiner has rejected Claim 62 under 35 U.S.C. § 103(a) as being obvious over Dowd. The Examiner has stated that Dowd does not disclose the bone particles being mixed with bone powder in a ratio up to 1:4, but that it would have been obvious to use a weight ratio up to 1:4 with the osteoimplant of Dowd.

None of Dowd's examples disclose using any bone powder at all. Example 3 actually teaches away from using bone powder. (Column 6, lines 53-56.)

It is well established that when a rejection of obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *B.F. Goodrich Co. v. Aircraft Braking Systems Corp.* (CAFC), 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 citing *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).

Dowd does not provide any suggestion, motivation, or even a hint of an osteoimplant containing elongate bone particles and bone powder in a ratio of about 1:4.

The Examiner further asserts that an ordinary person skilled in the art would have expected applicant's invention to perform equally well with the weight ratios taught by Dowd or the claimed weight ratio of up to 1:4 because both the Dowd mixture and the claimed invention perform the same function of reducing porosity or void volume of the implant. This wholly unsupported statement cannot be the basis for this rejection. Dowd teaches a void volume of at least about 37% and the currently claimed osteoimplant has a void volume of not greater than about 32%. As is explained on p.6, lines 1-4 of the specification of the current invention, it is the small void volume that provides the advantages of the current invention. This void volume of not greater than 32% is necessarily determined by the ratio of bone particles to bone powder utilized. By increasing the amount of bone powder as compared to bone particles in the ratio, e.g., up to 1:4, one would decrease the void volume of the resultant osteoimplant. One skilled in the art would appreciate

that if one wanted a void volume of greater than, e.g., 37%, they surely would use a ratio of less than 1:4 and most likely 1:0 to assure a greater void volume. Thus, one skilled in the art would be led away from the current invention by the teachings of Dowd. Therefore, in light of the above remarks, the Applicant believes that the rejection of Claim 62 has been overcome and thus respectfully requests allowance of Claim 62.

The Examiner has rejected Claims 66 and 68 under 35 U.S.C. § 103(a) as being obvious over Dowd in view of International Patent Publication WO 99/39757 to Boyce et al. ("Boyce et al."). The Examiner has stated that Dowd does not disclose the osteoimplant in laminate form or that there is at least one zone of impermeability to soft tissue ingrowth. The Examiner further states that Boyce et al. shows an osteoimplant having a laminate form and that the bone elements are crosslinked and that this crosslinkage provides an inherent zone of impermeability.

With regard to the Examiner's assertion that one skilled in the art would use a laminate taught in Boyce et al. for the osteoimplant of Dowd. There is nothing in Dowd to even remotely suggest or motivate one skilled in the art to modify the Dowd osteoimplant with the laminate of Boyce et al., as has been stated above, it is well settled that there must be some motivation or suggestion provided in the references to allow them to be used in a combination obviousness rejection. There is nothing to indicate that the high void volume implant of Dowd could be used successfully in a laminate structure. The laminate structure of Boyce et al. is facilitated by chemical linkages between surface exposed collagen. Dowd's elongate bone particles have been demineralized substantially, thus removing most of the surface exposed collagen that is needed in the Boyce et al. osteoimplant to

allow for the chemical linkage bonding occurring in a laminate form. Thus, one skilled in the art would be led away from Boyce et al. due to the fact that Dowd particles could not reasonably be expected to provide the necessary chemical bonding.

Furthermore, with regard to the Examiner's assertion that Boyce et al. inherently does not allow for soft tissue ingrowth due to the disclosed chemical bonds formed, nowhere does Boyce et al. disclose that the chemical linkages will provide for a zone of impermeability. On the contrary, Boyce et al. teaches that the osteoimplant has advantages over the prior art in that it has the "...ability to function as a carrier for and effectively diffuses one or more bone-growth inducing substances that promote new bone growth and/or accelerate healing." (p.5, lines 18-21.)

The Examiner has failed to provide any motivation or suggestion for the combination of Dowd and Boyce et al. There is no motivation for one skilled in the art to modify Dowd with Boyce et al. to arrive at the presently claimed invention.

In light of the foregoing remarks, the Applicant believes that the rejection of Claims 66 and 68 has been overcome and allowance of Claims 66 and 68 are respectfully requested.

In view of the foregoing, reconsideration and allowance by the Examiner of  
Claims 41-84 as presented herein are respectfully requested.

Respectfully submitted,



Jaksha C. Tomic  
Reg. No. 53,696  
Attorney for Applicants

DILWORTH & BARRESE, LLP  
333 Earle Ovington Blvd.  
Uniondale, New York 11553  
(516) 228-8484

JCT:mg